

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
Houston Division**

NATURAL ALTERNATIVES
INTERNATIONAL, INC.,

Plaintiff,

v.

WOODBOLT DISTRIBUTION, LLC, *et al.*,

Defendants.

Civil Action No. 11-4511

**NOTICE OF SUPPLEMENTAL AUTHORITY IN OPPOSITION TO
WOODBOLT’S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT
OF PLAINTIFF’S CROSS MOTION FOR SUMMARY JUDGEMENT**

At the August 28, 2012, conference, the Court raised certain questions regarding the patents-in-suit and the inventions in the context of defendant Woodbolt Distribution, LLC’s (“Woodbolt”) motion for summary judgment of invalidity and plaintiff Natural Alternatives International Inc.’s (“NAI”) cross motion for summary judgment upholding the patents. This supplemental filing provides the Court with additional responsive information and legal authority regarding those questions.

A. Validity of Dietary Supplement Patents

The Court asked whether beta-alanine could be the subject of a patent because it is a naturally occurring amino acid. In the context of the patents-in-suit, the beta-alanine used as a dietary supplement is man-made. The following are just a few examples where courts have found dietary supplement patents pertaining to natural substances found in the body to be valid:

1. In *Creative Compounds, LLC v. Starmark Laboratories*, 651 F.3d 1303 (Fed. Cir. 2011), the Federal Circuit affirmed that a patent claiming a creatine salt, where creatine is an amino acid derivative naturally present in

muscle tissue, was not invalid. The Court wrote that “[b]oth the [patents-in-suit] relate to innovations in dietary supplements and food products. These patents relate to creatine formulations that increase the bioavailability of creatine. Creatine is an amino acid derivative naturally present in muscle tissue. It serves as a central component of the metabolic system and provides energy for work and exercise performance. It assists in producing adenosine triphosphate (‘ATP’) during short bursts of high intensity exercise. The depletion of creatine has been associated with the onset of fatigue. Creatine is most commonly used by body builders looking for a steroid-free way of improving athletic performance.” *Id.* at 1306 (citations omitted).

2. In *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F.3d 1339 (Fed. Cir. 2006), the Federal Circuit affirmed that a patent claiming a carotenoid composition consisting essentially of substantially pure lutein crystals derived from plant extracts that contain lutein was not invalid, holding that “[l]utein is a carotenoid (i.e., an organic, naturally occurring pigment) that Kemin and PIVEG incorporate in dietary health supplements that they manufacture and distribute.” *Id.* at 1343.
3. The court in *Everett Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*, 573 F. Supp. 2d 855 (D.N.J. 2008), granted a preliminary injunction because the patent holder made a showing of likelihood of success that patents claiming prenatal nutritional supplements which contained vitamins and minerals, and methods of administering the supplements were valid.
4. In *ThermoLife Int’l, LLC v. Sechel Holdings, Inc.*, 2012 U.S. Dist. LEXIS 42419 (D. Ariz. Mar. 28, 2012), the court held that a patent to the dietary supplement creatine nitrate was valid and enforceable. As described by Woodbolt, creatine nitrate is the combination of a creatine molecule with nitric acid. (Dkt. No. 67 Ex. D). It is one of the ingredients contained in its C4 Extreme and M5 Extreme accused products in this case. (*Id.*).

B. New Use Of A Composition

NAI’s pending summary judgment briefs show that the dietary supplement inventions set forth in the patents-in-suit are not within the prior art. Because the prior art does not teach a

dietary supplement that reflects the functional relationship between supplementation and beta-alanine, there was no known compound with a new use. Regardless, a new use for a composition such as beta-alanine is patentable. The patent statute provides that “[w]hoever invents or discovers any new and useful process . . . or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor” 35 U.S.C. § 101. The Patent Act also defined the term “process” to mean a “process, art or method, *and includes a new use of a known process . . . composition of matter, or material.*” 35 U.S.C. § 100(b) (emphasis added). Accordingly, in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 347 F.3d 1367, 1372 (Fed. Cir. 2003), the Court cited § 100(b) in holding that a method of use patent was valid and infringed even though the compound was well known in the prior art. Thus, even if the human dietary supplement of the patents was already a well known composition, new uses such as those described in the patents-in-suit are patentable under the law.

For example, in *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001), the Court found that knowledge of a use does not confer upon the public the benefit of other uses for the same composition or structure. The Court rejected an argument that the claimed use of buspirone to treat sleep apnea was anticipated under patent law by its use for a different purpose – to treat anxiety. *Id.* at 1063. The prior art did not teach or suggest the new use of the drug on apnea patients. In the case currently before this Court, the prior art did not teach or suggest that the single amino acid beta-alanine could be used in a sufficient dosage for a continuous period to be effective in preventing the onset of muscular fatigue.

Another example is Sildenafil citrate, which was originally designed to lower blood pressure and treat angina. U.S. Patent No. 5,250,534 (“the ‘534 patent”) claimed the composition of matter and its use in treating angina, hypertension, heart failure or atherosclerosis. The patent

holder later discovered that the same chemical could also be used to treat a particular condition in males and obtained U.S. Patent No. 6,469,012 (“the ‘012 patent”) on the method of using this compound to treat erectile dysfunction in males. The resulting brand name product was Viagra[®]. Although the ‘012 patent was challenged on the grounds that the earlier ‘534 patent rendered the invention unpatentable, the Court found the ‘012 patent valid for the later discovered use. *Pfizer Inc. v. Teva Pharms. USA Inc.*, 803 F. Supp. 2d 409 (E.D. Va. 2011). Thus, a new use of the well known compound was held to be patentably distinct as a new invention that resulted in the ‘012 patent.

In addition, NAI’s patents contain several dependent claims covering a human dietary supplement that combines beta-alanine with other things, including creatine, L-histidine, carbohydrates and insulin, or insulin stimulating agents. (Claims 3, 5-9 in the ‘381 patent and Claims 13 and 14 in the ‘422 patent). These new combinations are patentably distinct. A patent claim covering the raw ingredient beta-alanine – standing alone – is different from patent claims that use beta-alanine together with something else as a dietary supplement. In other words, the dependent claims pertain to a new patentable composition and methods of use. There is no clear and convincing evidence that these claims are invalid.

C. How Beta-Alanine Works

The Court also questioned how beta-alanine works. Exhibits 9 and 10 of NAI’s reply on its cross motion (Dkt. No. 64) describe how the relevant science works. Generally, when exercising or physically working, the muscle cells of the body release hydrogen ions (H⁺), which cause the pH in muscles to drop (become more acidic) and increases fatigue. Ingesting the single amino acid beta-alanine over an extended period of time boosts the concentration of a H⁺ buffer inside the muscles. This buffer, known as carnosine, is a dipeptide consisting of beta-alanine and

another amino acid, L-histidine, connected via a peptide bond. In the muscles, carnosine absorbs H^+ and stabilizes the muscular pH. The inventors discovered that by ingesting the single amino acid beta-alanine as a dietary supplement in sufficient amounts over a continuous period¹ of time, a person will be able to buffer/absorb increased amounts of H^+ that are released during exercise and maintain muscles in an optimal pH range for longer periods of time.

While beta-alanine is a naturally occurring amino acid in the body, it is not normally found in the quantity that can be forced into the muscle by prolonged use.² Sufficient beta-alanine cannot be obtained from the diet alone (particularly if you are a vegetarian). For example, a person would have to eat 93 McDonald's Big Macs a day to obtain the equivalent amount contained in a single 3,200 mg supplement of beta-alanine.³ A person would have to eat **93 Big Macs every day** for a **continuous period** of time. There can be no doubt that NAI's inventors discovered a new, useful and patentable invention. The new method of using beta-alanine is also properly patentable.

¹ Before the inventors' discovery, science did not know that you could increase a human's endurance by feeding him beta-alanine over a period of time. Ingested beta-alanine goes into the blood stream where much of it is rapidly removed by the kidneys.

² By contrast, L-histidine is plentiful and consuming it would not be expected to lead to the increase in carnosine.

³ Cooked beef has 124 mg carnosine/100 grams of beef (<http://www.ncbi.nlm.nih.gov/pubmed/15941308>). A single Big Mac has 70 grams of beef (<http://www.nhs.uk/Livewell/Goodfood/Pages/red-meat.aspx>). Thus, a Big Mac has 86.8 mg of carnosine (226g/mol), which releases 34.18 mg beta alanine (89 grams/mol). Accordingly, one 3.2 gram daily supplement of beta-alanine is the equivalent to 93 Big Macs.

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CERTIFICATE OF SERVICE

I hereby certify that on September 6, 2012, a copy of the foregoing was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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